Message

From: Siedschlag, Gregory [Siedschlag.Gregory@epa.gov]
Sent: 6/30/2021 3:27:38 AM
To: Keigwin, Richard [Keigwin.Richard@epa.gov]
CC: Dunton, Cheryl [Dunton.Cheryl@epa.gov]; Ozmen, Shamus [Ozmen.Shamus@epa.gov]; Lara, Rhina [Lara.Rhina@epa.gov]
Subject: OCSPP IO review: The Intercept, Sharon Lerner re: malathion, DDL: 6/29

Importance: High

Hi Rick,

See our response below regarding malathion to The Intercept. We're a little behind on this one – it was due COB today. Your quick review in the morning would be appreciated!

Inquiry: **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

Background:
The 2000 Final Cancer Assessment Document for Malathion is available online.

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pronouns: he/him/his

From: Ozmen, Shamus <Ozmen.Shamus@epa.gov>
Sent: Tuesday, June 29, 2021 5:12 PM
To: Dunton, Cheryl <Dunton.Cheryl@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Siedschlag, Gregory <Siedschlag.Gregory@epa.gov>; Lara, Rhina <Lara.Rhina@epa.gov>
Subject: FW: OPP IO review: The Intercept (4th follow-up) re: malathion, DDL: 6/29

Hi Cheryl – For your review below is the follow-up regarding malathion. The other follow-up will be shared shortly.

Response:

Ex. 5 Deliberative Process (DP)

Background:
The 2000 Final Cancer Assessment Document for Malathion is available online.

On Jun 21, 2021, at 3:37 PM, Sharon Lerner <sharon.lerner@theintercept.com> wrote:

Hi Robert, Ken and Nancy-
Sorry there's one - hopefully last - thing I should run by you. After speaking with several people involved and reviewing the documents attached below, I noted the following about malathion. I welcome EPA's perspective on this:

In February 2000, a working group at the EPA classified malathion as "likely to be carcinogenic to humans" based on evidence that mice and rats exposed to it developed liver tumors. The designation would have required the agency to do a risk assessment that could have limited exposure to the chemical. But after it learned of the agency's proposed classification , Cheminova, the one of the manufacturers, hired a company to reinterpret the evidence and convened another meeting to discuss the carcinogenicity of malathion. Brian Dementi, a senior EPA toxicologist who was an expert on malathion and led the committee that supported its classification as a likely human carcinogen, was not invited — or even told about — this second meeting, at which the scientists paid to defend malathion suggested downgrading its status to "suggestive evidence of carcinogenicity," a classification that doesn't require a risk assessment.

Dementi wrote to Mike Leavitt and Stephen Johnson, then the EPA administrator and deputy administrator, laying out the evidence that malathion caused cancer and warning that if it was not classified as a likely human carcinogen, "public health will be endangered." Dementi suggested that the pesticide "should be re-assessed by pathologists not in the employ of the registrant." Later he wrote another letter to the EPA administrator, presenting the evidence that children were particularly susceptible to malathion.

Bill Hirzy, a scientist and an official in the union that represented DeMenti, remembers the pressure to give malathion a pass as intense. "When malathion was up for reregistration, when the heads of the various divisions who were looking at health effects were sitting around the table and planning to address the issue, the science advisor poked his head in the door and said 'this is a big-ticket pesticide and we don't want to have any problems,'" he said.

Despite the concerns that Dementi raised, malathion was given the less restrictive designation later that year.

Since then, mounting evidence has linked the pesticide to numerous cancers, including, including thyroid cancer, prostate cancer, and breast cancer. In 2015, the World Health Organization concluded that malathion is "probably carcinogenic to humans." And in 2017, the EPA itself found that 97 percent of federally protected species are likely harmed by it. Nevertheless, malathion remains classified as only having "suggestive evidence of carcinogenicity." Each year, about one million pounds of malathion are sprayed in the U.S.

<Dementi Critique of malathion PWG.pdf>
<BAD SLJ 06.20.05 EPA-HQ-OPP-2006-0618-0028.2[1].pdf>
<BAD SLJ 09.28.06 EPA-HQ-OPP-2006-0618-0028.1[1].pdf>
<PSI Grievance Post hearing brief.pdf>

Please get me all of the outstanding responses by Thursday.

Thank you,
Sharon

Sharon Lerner
Investigative Reporter
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PGP:
CB29 D9FF 9285 3205 087E 83A1 0C30 2F39 4F30 8BFE

> On Jun 21, 2021, at 1:21 PM, Sharon Lerner <sharon.lerner@theintercept.com> wrote:
>
> Hi Ken and Robert-
> I'd like to add one more question to my follow-ups:
> You mentioned in your response that 8,846 pesticide products (i.e., registrations) have been reviewed and accepted to meet the requirements of the REDs for the active ingredients in each product.
> My question is: how many are still awaiting review? i.e. 8,846 have been completed out of how many overall?
> Thanks,
> Sharon
>
> **Sharon Lerner**
> **Investigative Reporter**
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PGP:
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On Jun 18, 2021, at 2:40 PM, Daguillard, Robert <Daguillard.Robert@epa.gov> wrote:

Thanks Sharon. Ken will get back to you when we return to the office on Monday.

Enjoy the weekend – hopefully sunny where you are.

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From: Sharon Lerner <sharon.lerner@theintercept.com>
Sent: Friday, June 18, 2021 2:25 PM
To: Labbe, Ken <Labbe.Ken@epa.gov>
Cc: Press <Press@epa.gov>
Subject: Re: Questions about pesticide regulation

Hi Ken-
I have three follow-up questions:

When you say "Additionally, 12,056 pesticide products were cancelled during the Reregistration process," do you mean voluntarily cancelled - ie that the companies agreed not to reregister them? or involuntarily?

Re bifenthrin: you write that "The results from the special pharmacokinetic (PK) study support the use of an oral study to assess the carcinogenic potential of bifenthrin which would be protective of tumors following inhalation exposure." I am not sure what special pharmacokinetic (PK) study you are referring to. Did you mention this elsewhere in your response? Is this a reference to the subchronic inhalation study?

Re acetamiprid: I now unerstand that EPA never adopted the lower number - the 2.5 mg/kg day. So my question is: why wasn't Nguyen's memo considered or responded to in the file? Why didn't they change the number based on the statistical analysis of EPA's own statistician? If EPA believed his analysis to be incorrect, why wasn't there anything in the file correcting it?

Thanks,
Sharon

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PGP:
CB29 D9FF 9285 3205 087E 83A1 0C30 2F39 4F30 8BFE

On Jun 17, 2021, at 4:16 PM, Labbe, Ken <Labbe.Ken@epa.gov> wrote:

Hi Sharon, Please see our responses below:

1. I spoke to more than two dozen people for this story about pesticide regulation, including 12 who used to work at OPP. One of the subjects they consistently brought up was the influence of pesticide companies over the office. One person who worked at OPP for 40 years told me: "When you come into the lobby, many times there's a chemical or ag lobbyist there. They just bop in. They want to be your friend. They always complement you. But if you don't do what they want, they'll go to your boss or above your boss and say we can't work with you anymore. And you'll be taken of the project and put on something that's meaningless. I've seen it happen a number of times.
2. Regarding post-EPA employment of former OPP directors: I found that, since 1974,all seven former OPP directors who continued to work after leaving the agency (Dan Barolo, Marcia Mulkey, Steve Schatzow, Jim Jones, Steve Bradbury, Edwin Johnson, and Debra Edwards) went on to make money from the pesticide industry, either as direct employees, attorneys, or consultants. (The two other former directors who left the agency went directly into retirement.)

   One PhD level former EPA scientist told me he thought that the "revolving door" influenced the culture within OPP, saying "management officials are loathe to take any action that is likely to limit

their post-EPA employment opportunities"

3. One former OPP staffer told me that she felt the scientists in the office are overwhelmed by the amount of science they receive from registrants. "There aren't enough resources to go through all the studies. And there isn't enough time. What happens then is that people at EPA look at what the contractors said and decide whether to accept it or not. For the most part they just accept it."

RESPONSE:
EPA's mission to protect human health and the environment requires public trust and accountability. The agency is committed to ensuring our pesticide registration decisions are free from interference and that the agency's scientific integrity policy, which is a bedrock principle for the Biden-Harris Administration, is upheld. EPA is home to world-class scientists. As it has in the past, the agency will continue to ensure their voices and the role of science will guide its decisions going forward.

EPA relies on the best science available and evaluates information from multiplesources – pesticide companies, other governments, academia, and the published scientific literature – in its science evaluation process. Under Administrator Regan's leadership, EPA has a renewed commitment to protecting human health and the environment by making evidence-based decisions that rely on the input of career scientists.

The agency has a robust internal peer review process to ensure studies relied upon to evaluate pesticide safety are scientifically sound and appropriately integrated into risk assessments. Scientific conclusions and regulatory decisions are not determined by an individual scientist at EPA, but by consensus of expert multidisciplinary teams and scientific committees with

support from internal and/or external experts as needed. Additionally, each of the agency's committees have Standard Operating Procedures (SOPs) that permits scientists who disagree with committee decisions to file a minority (dissenting) opinion for the record.

4. Another subject that came up a lot was retaliation by managers toward OPP scientists who called attention to the hazards of pesticides. In one case, a former OPP scientists spoke about bifenthrin, which caused "a significantly higher incidence" of lung cancers when it was given to lab animals orally. While the scientist felt bifenthrin should have been subjected to extensive inhalation toxicity testing based on this finding and the fact that bifenthrin is a pyrethroid, a class of pesticides that are more toxic when inhaled as opposed to ingested, that testing was waived at the request of industry in 2012. Bifenthrin was only subject to a single inhalation toxicity study, which according to the scientist, "would absolutely not assess lung cancer formation." After raising the issue, the scientist said that their applications to relevant projects were denied, which they felt was retaliation for raising concerns about bifenthrin.

   Another statement I heard about retaliation from a former OPP scientist: "if you bring up something that's an inconvenient truth, you get circumvented for any kind of committee work that you would need to get a promotion. It is the unwritten rule that to get promotions all pesticides have to pass."

   RESPONSE:
   EPA's decision to recommend waiving a study is not determined by an individual scientist but by the consensus of the Hazard and Science Policy Council (HASPOC). This is an expert multidisciplinary group that considers both hazard and exposure using a weight-of-the-evidence risk-based approach to determine whether an animal study can be waived.

In the case of bifenthrin, HASPOC deliberated on the need for an inhalation study and the consensus decision was to waive the study However, the registrant did conduct a subchronic inhalation study that EPA subsequently reviewed and incorporated into the human health risk assessment for bifenthrin. The Cancer Peer Review Committee (CPRC) did note a higher incidence of lung tumors in female mice in some dose groups in the oral carcinogenicity study; however, there was no significant dose-related trend for these tumors. The results from the special pharmacokinetic (PK) study support the use of an oral study to assess the carcinogenic potential of bifenthrin which would be protective of tumors following inhalation exposure.

5. Are OPP staff members allowed to count crop/farm tours as/toward work time? If so, is there a limit to the number of hours that can be spent this way? And is there a limit to the amount of money sponsoring groups can spend per person on these tours?

   RESPONSE:
   Crop tours are typically held during the work week. EPA abides by all ethics statutes and maintains a culture of the highest ethical conduct with the amount of money sponsoring groups can spend on activities that EPA staff attend.

   Staff participation in crop tours have provided an increase in awareness and more educated discussions on the subject at hand such as farmworker issues.

6. QUESTION: Are bonuses for OPP staff sometimes based or partially based on the number of pesticides registered or reregistered?

   RESPONSE:
   EPA does not award bonuses to staff based on the number of pesticide registrations issued.

7. After Congressional hearings on pesticide regulation in the early 1980s,

EPA was mandated to review the registrations of every pesticide approved before November, 1984. This work was not completed until 2008.

RESPONSE:
EPA completed its review and met all reregistration deadlines set by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for food use reregistration and non-food use reregistration in 2006 and 2008, respectively. In September 2008, EPA completed a review of older pesticides – those initially registered before November 1, 1984 – to ensure that they met current scientific and regulatory standards. Approximately 1,150 pesticide active ingredients organized into 613 "cases" or related groups were subject to reregistration. As of FY2019, the latest reporting year for Reregistration Performance Measures, 8,846 pesticide products (i.e., registrations) have been reviewed and accepted to meet the requirements of the REDs for the active ingredients in each product. Most of these RED decisions required risk mitigation measures to ensure the products continued to meet the FIFRA safety standard. Additionally, 12,056 pesticide products were cancelled during the Reregistration process.

Through this reregistration process, authorized by the 1988 amendments to FIFRA, EPA called in and reviewed missing scientific studies and assessed human health and ecological effects using up-to-date science and input from stakeholders and the public.

In 1996, Congress unanimously passed the Food Quality Protection Act (FQPA), which amended FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA). FQPA established several requirements on tolerances to ensure when EPA sets tolerances that the pesticide can be used on food commodities with reasonable certainty of no harm. FQPA also

requires EPA to consider aggregate exposure and risk assessments (for multiple common mechanism groups of pesticides). To achieve the new safety standard, EPA refined its pesticide risk assessment methods and conducted multiple peer review panels to identify science policy issues that were key to the implementation of FQPA and tolerance reassessment. FPQA required EPA to implement the requirements by 2008, which the agency did meet.

The agency developed mitigation measures as needed to reduce risks of concern, such as limiting or eliminating certain uses of pesticides, requiring buffer zones around areas to be treated, or requiring protective clothing for pesticide workers. The results of EPA's reviews were summarized in Reregistration Eligibility Decisions (REDs). The agency is continuing to implement some of these decisions.

8. I say that EPA now manages more than 16,800 pesticide products and 1,200 active ingredients. QUESTION: Are these numbers, which I got from these slides, still accurate?

   RESPONSE:
   The numbers are accurate in that there are more than 16,800 registered pesticide products and more than 1,200 active ingredients.

9. In another case, an OPP staffer was asked to review the toxicity of a chemical called pelargonic acid in 2018. The toxicologist looked at the previous reviews of the chemical going back to 1997, which had found that it posed no health threat. But when the scientist looked up the archived raw data on which those reports were based, they found that several mice had developed leukemia and lymphoma after the chemical was applied to their skin. Concerned, the scientist wanted the Cancer Assessment Review Committee to reassess the chemical but, the

scientist said, a group of managers in OPP did not agree and were especially resistant because of the role of pelargonic acid, which in addition to being used as a weedkiller on its own, is also a co-formulant in Roundup. The scientist said that managers in OPP discouraged a reassessment of pelargonic acid from the cancer committee and made the process of requesting it difficult. After raising the concerns, the scientist reported facing increased scrutiny from their supervisor; being repeatedly threatened with disciplinary action; and being written up for failing to meet a deadline that was moved without their knowledge. QUESTION: Has pelargonic acid been reassessed by the CARC since 2018?

RESPONSE:
In May 2020, EPA issued the interim decision (ID) for pelargonic acid, which includes a thorough review of the best available science, as required under FIFRA. EPA has concluded that there is no new information that would require pelargonic acid to be reassessed by the Cancer Assessment Review Committee (CARC).

10. I spoke to biostatistician Lianne Shepperd about this paper, in which she described a "flawed analysis" of a 1972 paper commissioned by Dow and used by EPA to set risk tolerances for chlorpyrifos from 1984 and through the 1990s. Shepperd told me that Dow statisticians "conveniently left out one of the two baseline measurement days," in their analysis. "The outrageous thing was that the group they declared as NOEL was only that because they left out data from their analysis." Shepperd said that the paper continues to be influential, even though the EPA officially withdrew it from consideration in 2009 for ethical reasons. I asked her why she thought the EPA didn't detect what she described as "data falsification" and she told me: "EPA

didn't scrutinize it at the level I did. The science is hard. And once a study has been around, who goes back and looks after it's been accepted for 10, 15, or 20 years?"

RESPONSE:
Although the cited 1972 paper was used in previous risk assessment from 1984 and through the 1990s, this paper was not used in EPA's recent human health risk assessment for chlorpyrifos. EPA relies on the best available scientific information at the time in its science evaluation process. The most recent human health risk assessment relied on a human physiologically based pharmacokinetic/pharmacodynamic (PBPK/PD) model and acetylcholinesterase inhibition endpoint in humans, rather than NOEL from animal studies. As part of its risk analysis procedure, EPA monitors the scientific literature and incorporates additional studies, as appropriate, into its risk management decisions. Should robust scientific data demonstrate that EPA-registered uses of chlorpyrifos are posing risks of concern to the environment or human health, the agency will take appropriate action.

EPA's decisions for chlorpyrifos will be a transparent process driven by science and the rule of law, ensuring concerns raised regarding farmworker and children's safety will be fully addressed.

11. Another glyphosate-related issue: I was given a meta-analysis from ORD (which I've included as an attachment to the email) of several epidemiological studies looking at the relationship between glyphosate exposure and non-Hodgkin's lymphoma. That meta-analysis, which was written in the summer of 2016, noted that the four highest quality studies "all reported elevated risks of NHL associated with exposure to glyphosate even after controlling for other pesticide exposures"
and concluded that the studies "provide

suggestive evidence of carcinogenic potential between glyphosate exposure and increased risk of non-Hodgkin lymphoma." While that analysis was never published, EPA subsequently released reports in 2016 and 2017 that clearly drew on the earlier document — several sections have identical wording — but reached the opposite conclusion: that glyphosate is "not a probable carcinogen." One of the people I interviewed for the piece who was familiar with the study told me she believes that OPP's "cherrypicking" of the ORD report shows the need "for more firewalls to prevent political interference with the science."

RESPONSE:
The obtained document is a preliminary review, not a meta-analysis, that was used internally by EPA scientists to discuss available epidemiological studies several months prior to the completion of the agency's Issue Paper that was presented to the agency's external FIFRA Scientific Advisory Panel (SAP). Several iterations of text were prepared by different staff members during the process of drafting the Issue Paper to aid in discussions and the exchange of scientific opinions. As such, the document does not reflect subsequent staff discussions and revisions.

All the studies that evaluated the association between glyphosate exposure and non-Hodgkin lymphoma (NHL) available at the time of the SAP were included in the agency's weight-of-evidence evaluation in the Issue Paper and presented to the panel. Taking into consideration the SAP recommendations, the agency concluded that the strongest scientific support is for classification of glyphosate as "not likely to be carcinogenic to humans" and noted that that none of the panel members believed glyphosate should be classified as "likely to be carcinogenic to humans" or "carcinogenic to humans". Following the SAP, EPA published and reviewed additional studies, including an updated analysis of the Agricultural Health Study (AHS) cohort. As

part of this review, EPA statisticians also updated the NHL meta-analysis to include the newly published AHS cohort data and obtained a non-statistically significant meta-risk ratio. The additional studies and analyses did not impact the agency's conclusion. For more information, read the Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential.

EPA's cancer classification is consistent with other international expert panels and regulatory authorities, including the Canadian Pest Management Regulatory Agency, Australian Pesticide and Veterinary Medicines Authority, European Food Safety Authority, European Chemicals Agency, German Federal Institute for Occupational Safety and Health, New Zealand Environmental Protection Authority, and the Food Safety Commission of Japan.

12. In 2013, GAO and NRDC put out reports on conditional approval of pesticides. NRDC found that thousands had been approved through this loophole. Do you dispute that number? Do you have updated numbers on conditional approvals?

RESPONSE:
Under the pesticide law, a product may receive either conditional or unconditional approval from EPA.

In 2013, the Government Accountability Office (GAO) conducted a review of EPA's registration program as it relates to conditional registrations and reported that the total number of conditional product registrations granted was unclear, in part due to the limitations of EPA's databases and the agency's incorrect classification of some registrations as conditional.

Over the past years, EPA has taken steps to improve the accuracy of information about and internal tracking of conditional registration decisions as well as address the issues raised in the GAO report. These efforts are intended to promote consistency, enhance transparency, and improve

understanding of decision-making under FIFRA section 3(c)(7).

To view all pesticide active ingredients that were initially registered under the conditional registration authority in FIFRA sec. 3(c)(7)(C) from FY 2000 through August 2020, visit our website.

13. According to a 2007 memo written by an OPP statistician named James Nguyen, test of acetamiprid's developmental neurotoxicity showed that the chemical affected rats' developing brains. Although some male rats exposed to a mid-level dose of the pesticide had an impaired startle reflex, Exponent had dismissed the effects, according to Nguyen, who characterized the analysis as "the incorrect reporting of results." After he wrote his memo, the EPA reduced the official level at which acetamiprid is considered to have no effects from 10 to 2.5 mg/kg day in 2007. But in 2017, that NOEL level mysteriously officially returned to 10, even while Nguyen's memo remained stapled into the larger file on acetamiprid. QUESTION: Why did the NOEL for acetamiprid go back up to 10 mg/kg day in 2017?

RESPONSE:
EPA conducts an independent evaluation of a study submitted to support pesticide registration and the study review is summarized in a data evaluation record (DER). This review employs a weight-of-evidence approach that considers both biological and statistical significance and is described in a memo entitled ACETAMIPRID: Data Evaluation Record for Acetamiprid Developmental Neurotoxicity Study and EPA Response to Rebuttals Submitted by Nisso America dated Feb 11, 2008".

In addition, the original DER for the acetamiprid developmental neurotoxicity (DNT) study established the maternal and offspring no observed adverse effect level (NOAEL) at 10 mg/kg/day (the lowest observed adverse effect level (LOAEL) = 45 mg/kg/day). This conclusion considered the

statistical analyses for the auditory startle response data described in the 2007 memo referenced in this inquiry, as well as historical control data and the acetamiprid toxicity profile. The NOAEL and LOAEL values for the acetamiprid DNT study have not changed since the original review was completed in 2008 and have been consistently reported in acetamiprid risk assessments as 10 and 45 mg/kg/day, respectively.

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